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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,361	08/11/1999	BURKHARD SCHLUTERMANN	4-21233/A	4260

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THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT, NJ 079011027

EXAMINER

SPEAR, JAMES M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 05/20/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/367,361

Applicant(s)
SCHLUTERMANN, B

Examiner
JAMES M. SPEAR

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 12, 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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The indicated allowability of claims 11-15 is withdrawn in view of a new grounds of rejection.

Prosecution on the merits of this application is reopened on claims 11-15 considered unpatentable for the reasons indicated below:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourquin US 5,472,714.

The Bourquin reference teaches color-stable tablets comprising: (1.) A therapeutic drug oxcarbazepine tablet core prepared by a compacting method. Dry granulation is used followed by compressing the active agent with the adjuncts to form larger objects such as coarse lumps, followed by comminuting these by grinding and compressing the grinding stock to tablet cores. See column 2, lines 14-

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27, 52 to column 3, line 15. and (2.) a hydrophilic, permeable outer layer containing white pigments in combination with iron (II) oxide pigments. See Abstract.

The difference between the claimed invention and the teachings of the Bourquin reference is that applicant includes the particle size distribution for the oxcarbazepine which is described in the specification as preferred, not as critical nor established as critical to the composition, affording an unexpected property. The reference uses the same drug after mechanically grinding to fine particles, but fails to mention the particle size distribution. All of the examples in the specification use oxcarbazepine as the active drug in association with other excipients to form a mixture, which is ground in conventional manner, just as the reference process does. Applicants examples fail to disclose the particle size distribution and establish the unexpected property of the tablets provided by the claimed particle size distribution. It is generally accepted in the art that drugs in the form of particles are easily dispersed or dissolved in the system for its quick action. The mere fact that applicant discloses to use a formulation of oxcarbazepine comprising oxcarbazepine having preferable median particle sizes of the finely ground form does not support a conclusion of criticality of the particle size distribution. (Page 1, lines 19-22). *In re*

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Courtright, 153 USPQ 735, 740 (CCPA 1967). *In re Shepard*, 50 CCPA 1439, 319 F. 2d 194, 138 USPQ 148, and cases cited therein. Even if applicant established an unexpected observation that the drug particles of the claimed size distribution are readily dissolved in the system such an observation is not unexpected, since it is generally accepted in the art that drugs should be in finely ground state to be immediately available to the system at the point of desired delivery. The composition of the outer layer in applicant's claimed tablets is the same as the composition of the outer layers of the reference tablets, whether one calls the outer coating as one-layer or two-layer. It is well known in the art that drugs in the form of finite particles are easily dispersed, dissolved and absorbed into the system. Applicant uses the same conventional grinding process as the reference. The particle size distribution in the reference tablet is expected to be essentially identical with or similar to the applicant's claimed size distribution.

It would have been obvious to one of ordinary skill in the art to follow the teachings of Bourquin and claim the same tablet with a core of oxcarbazepine and other excipients and an outer layer comprising white pigments and iron oxide pigments and include a non-critical particle size distribution for the core drug within

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the range of applicant's. The motivation being suggested by the general state of the art teaching the same core drug oxcarbazepine with excipients being subjected to some degree of grinding to reduce the drug into fine particles, mechanically compacted into tablets and coated. The finite particles having particle size distributions as cited above would provide for optimum absorption and bioavailability of the oxcarbazepine.

Claims 11-15 are rejected. Claims 1-10 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Spear whose telephone number is 703 308 2457. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308 2927. The fax phone number for the organization where this application or proceeding is assigned is 703 305 3592 or 308 4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

James M. Spear

May 9, 2002

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
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